K131645

alfa SCIENTIFIC DESIGNS, INC
13200 Gregg Street
Poway, CA 92064 – USA
Telephone: 858-513-3888 ♦ Fax: 858-513-8388

ISO 13485 MEDICAL DEVICES

510(k) Summary

Safety and effectiveness as required by 21 CFR 807.92

Manufacturer and Submitter	**Name:**	Alfa Scientific Designs, Inc.
	Address:	13200 Gregg Street Poway, CA 92064 Telephone: 858-513-3888 Fax: 858-513-8388
	Contact Person:	Naishu Wang, MD, Ph.D. Email: wnss@alfascientific.com 858-413-1266 (direct)

OCT 07 2013

Device Name	**Trade Name:** Instant View® Multi-Drug of Abuse Urine Test Cup Instant View® Multi-Drug of Abuse Urine Test Panel **Common Name:** Immunoassay, Drug of Abuse Screening Urine Test **Classification Name:** Amphetamine Test System, Barbiturate Test System, Benzodiazepine Test System, Cocaine and Cocaine Metabolite Test System, Methamphetamine Test System, Opiate/ Morphine Test System, Cannabinoid Test System, Tricyclic Antidepressant Drugs Test System, Phencyclidine Test System **Product Code:** DKZ (21 CFR 862.3100), DIS (21 CFR 862.3150), JXM (21 CFR 862.3170), DIO (21 CFR 862.3250), DJC (21 CFR 862.3610), DJG (21 CFR 862.3650), DJR (21 CFR 862.3620), LCM (21 CFR 862.3100), LFG (21 CFR 862.3910), LDJ (21 CFR 862.3870)
Date of Summary Preparation	09-19-2013

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Predicate Devices	**INSTANT-VIEW® Multi-Drug of Abuse Urine Test (K063545)** Manufacture is Alfa Scientific Designs, Inc.

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Device Description

The Instant View® Multi-Drug of Abuse Urine Test Cup and the Instant View® Multi-Drug of Abuse Urine Test Panel are one-step lateral flow chromatographic immunoassays. Each device consists of any combination of one to twelve individual test strip(s) for the analyte(s) being tested. Each test strip in the device consists of 1) a conjugate pad containing colloidal gold coupled with the anti-drug antibodies and 2) nitrocellulose membrane containing a test line (T line) coated with the conjugated drug antigen and a control line (C line). The C line serves as an internal quality control of the system and appears as a burgundy-colored band during the test regardless of the presence of the drug.

Intended Use

Instant View® Multi-Drug of Abuse Urine Test Cup

The Instant View® Multi-Drug of Abuse Urine Test Cup is a rapid, qualitative immunoassay for the detection of one or more of the following drugs in human urine. This device is for over the counter use and may detect any combination of the drugs or drug metabolites at or above the specified cut-off level listed below.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/mL
BAR	Barbiturates	200 ng/mL
BZD	Benzodiazepine	300 ng/mL
COC	Cocaine	300 ng/mL
MDMA	MDMA or Ecstasy	500 ng/mL
MET	Methamphetamine	1000 ng/mL
MTD	Methadone	300 ng/mL
MOR	Morphine/Opiates	2000 ng/mL
OXY	Oxycodone	100 ng/mL
PCP	Phencyclidine	25 ng/mL
TCA	Tricyclic antidepressants	1000 ng/mL
THC	Marijuana	50 ng/mL

The drug tests will provide a preliminary result only. A more specific, alternative chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and High-Performance Liquid Chromatography (HPLC), or the like are the preferred confirmation methods for most drugs in urine. Clinical consideration and professional judgment should be applied to any drug test result, particularly when evaluating preliminary positive results.

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Instant View® Multi-Drug of Abuse Urine Test Panel

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Similarity to Predicate Devices	• Devices are one-step lateral-flow chromatographic immunoassays. • Devices are intended to provide qualitative detection of drug abuse. • Devices are in-vitro diagnostic devices for OTC use. • Devices have built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly. • Devices consist test strips, each for one analyte.
Technological Characteristics	The proposed multi-drug urine test devices use the same technology and formulations for the detection of the drugs as individual test devices. The performance characteristics, such as accuracy, reproducibility, sensitivity and specificity of this drug of abuse test are the same as the predicate device.
Conclusion	The proposed test is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 7, 2013

Alfa Scientific Designs
c/o Naishu Wang, Ph.D.
13200 Gregg St.
POWAY CA 92064

Re: K131645
Trade/Device Name: Instant-View Multi-Drug of Abuse Urine Test Cup
Instant-View Multi-Drug of Abuse Urine Test Panel
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DIS, JXM, DJC, DJG, DJR, LCM, LFG, LDJ, DIO
Dated: September 23, 2013
Received: September 24, 2013

Dear Dr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131645

Device Name: Instant-View Multi-Drug of Abuse Urine Test Cup
Instant-View Multi-Drug of Abuse Urine Test Panel

Indications for Use:
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Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles -S
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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) k131645

Indications for Use

510(k) Number (if known): k131645

Device Name: Instant-View Multi-Drug of Abuse Urine Test Cup
Instant-View Multi-Drug of Abuse Urine Test Panel

Indications for Use:
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